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10/597,674	08/03/2006	Thomas Schnelle	B1180/20058	4776

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EXAMINER
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DIETERLE, JENNIFER M

ART UNIT	PAPER NUMBER
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1795

NOTIFICATION DATE	DELIVERY MODE
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03/29/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/597,674	<b>Applicant(s)</b> SCHNELLE ET AL.	
	<b>Examiner</b> Jennifer Dieterle	<b>Art Unit</b> 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 25-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/03/06, 02/07/07</u> .                                      | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 1-24 have been canceled.

Claims 25-40 are being examined.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 25-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 recites a first manipulation apparatus and a second manipulation apparatus, but then goes on to recite that the first and second manipulation apparatus have a common electrode arrangement. It is unclear whether there are three separate and distinct manipulation apparatuses, two manipulation apparatuses, or just one apparatus given the first and second manipulation apparatus have a common electrode arrangement. Since claims 26-35 depend from claim 25, they to are rejected.

2. Claims 26 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26 recites that the common electrode arrangement stated in claim 25, that contains the first and second manipulation apparatus, is a "third manipulation apparatus." However, since it is unclear from claim

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25 whether there are three distinct manipulation apparatuses, two manipulation apparatuses, or one common manipulation apparatus. Since claim 28 depends from claim 26, it is rejected.

3. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 recites that the common electrode arrangement has at least one electrode that is a component of the first manipulation apparatus as well as a component of the second manipulation apparatus. It is unclear how the common arrangement can have an electrode that is a component of the first and second manipulation apparatus since the common arrangement is located in the branch area and the first and second apparatuses are located in the flow channel. If there are common electrodes, it is not clear how the first and second apparatuses can be in the branch channel as recited in claim 25 as they would also have to be in the branch area.

4. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 28 recites that the third electrode arrangement is a centering apparatus that centers the particles in the carrier channel. Since the common arrangement is located in the branching area, it is unclear how it can function as a centering apparatus. Applicant's in their specification at section 0060 note that a centering apparatus is located in the flow channel, therefore, it is unclear why there would be a centering apparatus located in the branch channel since the purpose of a

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device in the branch channel would be to direct the particles into one of the branching areas. If a particle is centered, it will not flow into either branch.

5. Claim 30 recites the limitation "electrode arrangement" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim. Given the rejection above concerning claim 25, since it appears that there can be up to three electrodes, it is not clear as to which "electrode arrangement" is being referred to in claim 30.

6. Claim 31 recites the limitation "centering unit" in line 2 and 4. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 32 recites the limitation "first measuring station" in line 1. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 33 recites the limitation "second measuring station" in line 1. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 34 recites the limitations "actuation unit", "first measuring station", "second measuring station" in lines 1-5. There is insufficient antecedent basis for these limitations in the claim.

10. Claim 36 recites the limitation "common electrode arrangement" in line 10. There is insufficient antecedent basis for this limitation in the claim.

11. Claims 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 36 recites a common electrode arrangement in line 10, in addition to an electrode arrangement in lines 4 and 7. It is unclear whether

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there is one electrode arrangement or two separate arrangements in the microfluidic device. Since claim 37 and 38 depend from claim 36, they to are rejected.

12. Claims 39 and 40 provide for the use of the microfluidic system of claim 25, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claims 39 and 40 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). MPEP 2173.05 Q.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 25, 29-31 and 34-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Muller et al. (Biosensors & Bioelectronics 14, 1999).

Regarding claims 25, 35 and 40, Muller et al. teach a microfluidic device and method of sorting using the device comprising:

- At least on carrier flow channel with particles suspended therein;
- A branching area which branches into two conduits (see figure 5 on page 250 showing flow channel and branch area, also see section 4.4);
- A funnel, aligner, cage (i.e. fix particles), and funnel all arranged in the flow channel (see figure 5, letters F, A, C and F);
- A sorter arranged in the flow channel (i.e. particle gate; see figure 5, letter S); and
- The sorter has a “common portion” that extends into the branching area (see figure 5).

Regarding claim 29, Muller et al. teach a microfluidic device that can comprise an electrode arrangement wherein an electrode array can comprise multiple deflection electrodes (i.e. funnel electrodes) located upstream and a field cage comprising arrow

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shaped electrodes that are aligned in opposite direction to the direction of carrier flow (see figures 5 and 6, see section 4.3).

Regarding claim 30, Muller et al. teach independent control of the different manipulation elements (i.e. separately actuated; section 3.2.2, page 251) and that electrode arrangements can have four six or eight electrodes (see figures 4-6 showing electrode arrangements).

Regarding claim 31, Muller et al. teach that a field cage can comprise eight electrodes (section 4.3) and the aligner (i.e. centering unit) located upstream from the field cage comprises at least four electrodes (see figure 4) wherein these electrodes work together.

Regarding claims 34 and 39, Muller et al. teach a microfluidic device which can be used in combination with fluorescence detection techniques and a wide range of other techniques (section 5) and the use of an actuation unit for actuating the electrode arrangement (section 3.2.2). Additionally, Muller et al. teach that the microsystems are for optical analysis of single cells and particles wherein a trapped particle (i.e. located in a field cage) can be analyzed and after analysis the particle can be divided into two fractions (i.e. sorted)(section 1, i.e. there is at least one measuring station that analyzes particles fixed in the filed cage) and the electrode in the sorter are actuated based upon the results of the analysis at the field cage.



Regarding claim 36, Muller et al. teach a method for actuating a microfluidic device comprising:

- Electrical actuation of an electrode arrangement to suspend particles in the carrier (i.e. particle cage, see figure 5, letter C);  
and
- Electrical actuation of an electrode arrangement to sort suspended particles in the branching area (see figure 5 letter S).

Regarding claims 37 and 38, Muller et al. teach a microfluidic device which can be used in combination with fluorescence detection techniques and a wide range of other techniques (section 5) and the use of an actuation unit for actuating the electrode arrangement (section 3.2.2). Additionally, Muller et al. teach that the microsystems are for optical analysis of single cells and particles wherein a trapped particle (i.e. located in a field cage) can be analyzed and after analysis the particle can be divided into two fractions (i.e. sorted)(section 1, i.e. there is at least one measuring station that analyzes particles fixed in the filed cage) and the electrode in the sorter are actuated based upon the results of the analysis at the field cage.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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15. Claims 26, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (Biosensors & Bioelectronics 14, 1999) in view of Tyvoll et al. (US 2005/0178700 A1).

Regarding claim 26, Muller et al. teach a microfluidic device comprising multiple electrode arrangements as described in claim 25 above; however, Muller et al. does not specifically teach that the common portion of the sorter forms a third separate manipulation apparatus.

Tyvoll et al. teach a device for sorting particles that can comprise a flow channel 54 and a branching area with a plurality of branch channels 64,66 (figure 2; paragraphs [0022-25]). Tyvoll et al. teach that a selective transport mechanism 76 (i.e. an arrangement in the branching area) can be configured to selectively move one or more particles into the respective branch channel and can be configured to operate concurrently with mechanism 74 (paragraphs [0030-35]) which can be an electrode array for dielectrophoretic movement (paragraph [0029]). Tyvoll et al. teach that the use of sorters may substantially increase throughput of particle sorting and help to characterize cells of interest in samples (abstract and paragraph [0012]).

Therefore, it would have been obvious to one skilled in the art to modify the device of Muller et al. to include a *separate* third sorting mechanism in the branch channel that can be configured to operate concurrently with electrode mechanism located upstream as taught by Tyvoll et al. because the use of sorters may substantially increase throughput of particle sorting and help to characterize cells of interest in samples (abstract and paragraph [0012]).

Regarding claims 32 and 33, Muller et al. teach a microfluidic device which can be used in combination with fluorescence detection techniques and a wide range of other techniques (section 5) and that cell behavior was monitored via a microscope (section 3.2.2). Additionally, Muller et al. teach that the microsystems are for optical analysis of single cells and particles wherein a trapped particle can be analyzed and after analysis the particle can be divided into two fractions (section 1, i.e. the second measuring station that analyzes particles fixed in the filed cage), but does not specifically note a first measuring station.

Tyvoll et al. teach a device for sorting particles that can comprise a flow channel 54 and a branching area with a plurality of branch channels 64,66 (figure 2; paragraphs [0022-25]). Tyvoll et al. teach that a selective transport mechanism 76 (i.e. an arrangement in the branching area) can be configured to selectively move one or more particles into the respective branch channel and can be configured to operate concurrently with mechanism 74 (paragraphs [0030-35]) which can be an electrode array for dielectrophoretic movement (paragraph [0029]). Tyvoll et al. teach that the use of sorters may substantially increase throughput of particle sorting and help to characterize cells of interest in samples (abstract and paragraph [0012]). Tyvoll et al. teach a particle sorter that includes a *sensor* 72 that can be located upstream from the sorter located in the branch area and configured to sense a property of a particle. Tyvoll et al. teach that the sensor may be a single sensor *or a plurality of sensor elements* (paragraphs [0024-25]). The sensor can be an optical sensor, electrical or

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magnetic. The sensor may include and/or function with a plurality of mechanisms for moving particles such as selective and nonselective mechanisms 74,76 (paragraph [0026]).

Therefore, it would have been obvious to one skilled in the art to modify the sensor apparatus of Muller et al. to include an additional sensor (i.e. first measuring stations) in the carrier flow prior to the sorting apparatus located at the branch area as taught by Tyvoll et al. because a sensor will provide properties of particles located at a plurality of positions along the channel prior to the sorting apparatus in order to achieve effective separation of particle in the branching area.

16. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (Biosensors & Bioelectronics 14, 1999) in further view of Tyvoll et al. (US 2005/0178700 A1) and Fuhr (US 6,440,285 B1).

Regarding claim 27, Muller et al. teach an electrode arrangement wherein in the branching area is located a "common portion" of the second manipulation apparatus, therefore, the "common portion" has at least one electrode that is a component of the second manipulation apparatus.

Muller et al. does not specifically teach that the "common portion" has at least one electrode that is a component of the first manipulation apparatus as well as a component of the second manipulation apparatus. Regarding the 112 rejection above, this claim is being interpreted as the "common portion" can perform as either a particle

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sorter or field cage in that it has at least one electrode component of the first manipulation apparatus (i.e. field cage) and a component of the second manipulation apparatus (i.e. particle sorter) as noted in applicant's specification at section 0067.

First, Tyvoll et al. teach a device for sorting particles that can comprise a flow channel 54 and a branching area with a plurality of branch channels 64,66 (figure 2; paragraphs [0022-25]). Tyvoll et al. teach that a selective transport mechanism 76 (i.e. an arrangement in the branching area) can be configured to selectively move one or more particles into the respective branch channel and can be configured to operate concurrently with mechanism 74 (paragraphs [0030-35]) which can be an electrode array for dielectrophoretic movement (paragraph [0029]). Tyvoll et al. teach that the use of sorters may substantially increase throughput of particle sorting and help to characterize cells of interest in samples (abstract and paragraph [0012]).

Second, Fuhr teaches a multi-electrode arrangement similar to that of Muller et al. for the arranging and positioning of objects in a flow channel (abstract). Fuhr specifically teaches the use of a field cage, multielectrode arrangement, which can be selectively actuated as either a field cage or a particle sorter (col. 2 and 4). The potentials of the electrodes can be chosen to either have a closed field cage that traps particles or an open field cage that directs particle movement in a certain direction. Fuhr teaches that the use of this field cage helps in the positioning objects and provides new level of control (col. 2). Fuhr teaches that the invention can be utilized with any electrode arrangement to create field cages, independently of the concrete electrode form or configuration (col. 3). The electrode arrangement is intended for coupling

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particles into and out of a particle stream (col. 6). The electrode arrangement of Fuhr can function as a field cage or particle sorter and would therefore have an electrode arrangement that comprises one electrode that is a component of the first manipulation apparatus (i.e. field cage) as well as a component of the second manipulation apparatus (i.e. particle sorter).

Therefore, it would have been obvious to one skilled in the art to modify the device of Muller et al. to include a *separate* third sorting mechanism wherein the third mechanism can function as a field cage or particle sorter and would therefore have an electrode arrangement that comprises one electrode that is a component of the first manipulation apparatus (i.e. field cage) as well as a component of the second manipulation apparatus (i.e. particle sorter) as taught by Fuhr and locate this third arrangement in the branch channel that can be configured to operate concurrently with electrode mechanism located upstream as taught by Tyvoll et al. because the use of sorters may substantially increase throughput of particle sorting and help to characterize cells of interest in samples (abstract and paragraph [0012]).

Regarding claim 28, Muller et al. teach a microfluidic device comprising multiple funnel electrode arrangements in combination with a field cage electrode arrangement in which the funnel centers particles in the carrier flow channel (see figure 5, page 252).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dieterle whose telephone number is (571) 270-7872. The examiner can normally be reached on Monday thru Friday, 8am to 5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/  
Supervisory Patent Examiner, Art Unit 1753

JMD  
3/22/10